UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	24-009-TB
First Inventor or Application Identifier	NOGAMI
Title	AN ORALLY ADMINISTERED AGENT AND AN ORALLY ADMINISTERED AGENT/SUPPORTING SUBSTRATE COMPLEX
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Commissioner for Patents
Mail Stop Patent Application
Arlington, VA 22202

1. [ ] * Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original and a duplicate for fee processing)
2. [X] Specification [Total Pages 49]
   - -Descriptive title of the Invention
   - -Cross Reference to Related Applications
   - -Background of the Invention
   - -Summary of the Invention
   - -Brief Description of the Drawings
   - -Detailed Description of the Preferred Embodiment
   - -Claims
   - -Abstract of the Disclosure
3. [X] Drawing(s) (35 U.S.C. 113) [Total Sheets 5]
4. Oath or Declaration [Total Sheets]
   - a. [ ] Newly executed (original or copy)
   - b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) (for continuation/divisional with Box 16 completed)
     - i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

5. [ ] Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   - a. [ ] Computer Readable Copy
   - b. [ ] Paper Copy (identical to computer copy)
   - c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R. § 3.73(b) Statement (When there is an assignee) [ ] Power of Attorney
9. [ ] English Translation Document (if applicable)
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) (should be specifically itemized)
13. [ ] *Small Entity Statement(s) (PTO/SB/09-12) [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) (if foreign priority is claimed)
15. [ ] Other: .....

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:
[X] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: PCT/JP02/03920
Prior application information: Examiner _____ Group/Art Unit: _____
For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[X] Customer Number or Bar Code Label 23400 (Insert Customer No. or Attach bar code label here) or [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone	(703) 707-9110	Fax	(703) 707-9112

Name (Print/Type)	DAVID G. POSZ	Registration No. (Attorney/Agent)	37,701
Signature		Date	October 23, 2003

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Arlington, VA 22202. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: NOGAMI	Atty. Dkt.: 24-009-TB
Serial No.: 10/690,811	Art Unit: 1615
Filed: October 23, 2004	Examiner: EL FAXED
Title: ORALLY ADMINISTERED AGENT AND AN ORALLY ADMINISTERED AGENT/SUPPORTING SUBSTRATE COMPLEX	

Mail Stop: Office of Initial Patent Examination
Filing Receipt Corrections
Commissioner for Patents
Alexandria, VA 22314

Date: December 8, 2005

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. 571-273-8300 on December 8, 2005.

Typed Name: DAVID G. POSZ

Signature: [signature]

REQUEST FOR CORRECTED FILING RECEIPT

Sir:

Please correct the filing receipt (copy to follow with indicated corrections) for the above-referenced patent application, and generate a corrected filing receipt. Copies of as-filed Form PTO/SB/05 and declarations are attached herewith for your references.

Please charge any unforeseen fees that may be due to Deposit Account No. 50-1147.

Copy

Respectfully submitted,

[signature]

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/690,811	10/23/2003	1615	1190	24-009-TB	5	12	1

23400
POSZ & BETHARDS, PLC
11250 ROGER BACON DRIVE
SUITE 10
RESTON, VA 20190

CONFIRMATION NO. 5426
UPDATED FILING RECEIPT

OC000000012268831

- Copy -

Date Mailed: 04/05/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s) x
Ei Ji Nogami, Saitama-shi, JAPAN;
Eiji

Domestic Priority data as claimed by applicant
This is a CON of PCT/JP02/03920 04/19/2002

Foreign Applications
JAPAN 2001-125804 04/24/2001
~~JAPAN PCT/JP02/03920 04/19/2002~~

If Required, Foreign Filing License Granted: 01/23/2004

Projected Publication Date: 07/15/2004

Non-Publication Request: No

Early Publication Request: No

Title

Orally administered agent and an orally administered agent/supporting substrate complex

Preliminary Class

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Eiji NOGAMI	Atty. Dkt.: 24-009-TB
Serial No.: 10/690,811	Art Unit: 1616
Filed: 10/23/2003	Examiner: Edward J. Webman
Title: AN ORALLY ADMINISTERED AGENT AND AN ORALLY ADMINISTERED AGENT/SUPPORTING SUBSTRATE COMPLEX	

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

Date: 30 October 2007

Copy

VOLUNTARY AMENDMENT

Dear Sir:

The following amendments and remarks are submitted in response to the Official action mailed on August 1, 2007, which set forth a three-month period for response, making the request for continued examination (RCE) filed together herewith due on or before November 1, 2007. Prior to an examination of this application based on the RCE filed together herewith, please amend the above-identified application as follows.

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the Listing of Claims that begins on page 3 of this paper.

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE SPECIFICATION:

Please insert the following heading and the paragraph between page 1, lines 3 and 4:

-- CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of International Application No. PCT/JP02/03920 filed on April 19, 2002, which application was not published in English, and which is based upon and claims the benefit of Japanese Patent Application No. 2001-125804 filed on April 24, 2001, the contents of which are incorporated herein by reference. --

LISTING OF CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Please amend claims 1 and 13 as follows.

1. (Currently amended) An orally administered agent free of a bioadhesive layer, comprising a drug-containing layer and a water-swellable gel-forming layer,

wherein said water-swellable gel-forming layer is provided as an outermost layer of said orally administered agent, and

the drug of the drug-containing layer is released in a digestive tract.

2. (Original) The orally administered agent according to claim 1, wherein said orally administered agent is a film-shaped preparation.

3. (Original) The orally administered agent according to claim 2, wherein said water-swellable gel-forming layer contains a water-swellable gel-forming agent and a film-forming agent.

4. (Original) The orally administered agent according to claim 3, wherein said water-swellable gel-forming agent is a cross-linked carboxyvinyl polymer, and said film-forming agent is a polyvinyl alcohol.

5. (Original) The orally administered agent according to claim 4, wherein said cross-linked carboxyvinyl polymer is a carboxyvinyl polymer cross-linked by a polyvalent metal compound.

6. (Previously presented) The orally administered agent according to claim 3, wherein the content of said water-swellable gel-forming agent in said water-swellable gel-forming layer is 15 to 70 wt%, and the content of said film-forming agent in said water-swellable gel-forming layer is 30 to 85 wt%.

7. (Previously presented) The orally administered agent according to claim 1, wherein said water-swellable gel-forming layer can mask the taste and/or smell of a drug contained in said drug-containing layer.

8. (Previously presented) The orally administered agent according to claim 1, wherein said drug-containing layer contains an edible polymer as a base.

9. (Original) The orally administered agent according to claim 8, wherein said edible polymer is cellulose and/or a cellulose derivative.

10. (Previously presented) The orally administered agent according to claim 8, wherein the content of said edible polymer in said drug-containing layer is at least 20 wt%.

11. (Previously presented) An orally administered agent/supporting substrate complex comprising the orally administered agent according to any one of claims 1 to 10, and a

supporting substrate that supports the orally administered agent, wherein said orally administered agent is provided on said supporting substrate either directly or via an intermediate layer.

12. (Previously presented) The orally administered agent/supporting substrate complex according to claim 1, wherein said supporting substrate has a gripping part and a mouth-inserting part, and said orally administered agent is provided on said mouth-inserting part.

13. (Currently amended) An orally administered agent free of a bioadhesive layer comprising a drug-containing layer and a water-swellable gel-forming layer, ~~wherein~~ said water-swellable gel-forming layer ~~is~~ being provided as an outermost layer of said orally administered agent, ~~and wherein~~ the agent ~~can be~~ being swallowed without getting stuck in a trachea, and the drug of the drug-containing layer being released in a digestive system.

REMARKS

In part 12 of the Office Action Summary, none of the boxes are checked. However, the applicant filed a certified copy of the priority document on April 10, 2007, together with a priority claim. The PAIR system shows that the priority document was received. Applicant (Eiji NOGAMI) respectfully requests that the next communication from the Patent Office kindly acknowledge receipt of the claim for priority under 35 U.S.C. §119 and receipt of the certified copy of the priority document.

The foregoing amendments amended the beginning of the present specification disclosure to identify prior applications. Claims 1 and 13 were amended in the foregoing amendments to define that the drug of the drug-containing layer is released in a digestive system. This aspect of applicant's invention is described on page 14, line 24 to page 15, line 5; page 35, line 9 *et seq.* and elsewhere in the present specification disclosure. The Official action mailed on August 1, 2007 withdrew claims 11 and 12 as directed to a non-elected invention. Accordingly, claims 1-10 and 13 are pending in the application for consideration by the examiner. Applicant respectfully requests reconsideration and allowance of these claims for at least the following reasons.

Claims 1-10 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,456,745 of Roreger *et al.* (Roreger). This rejection is set forth on page 2 of the Official action. Applicant respectfully submits that the inventions defined in claims 1-10 and 13 are patently distinguishable from the teachings of Roreger within the meaning of 35 U.S.C. §102 or 35 U.S.C. §103 for at least the following reasons.

The teachings of Roreger do not contemplate or suggest, *inter alia*, an orally administered agent free of a bioadhesive layer, comprising a drug-containing layer and a water-swellable gel-forming layer, the water-swellable gel-forming layer being provided as an

outermost layer of said orally administered agent, *and the drug of the drug-containing layer being released in a digestive tract*, as required in present claims 1 and 13. Accordingly, applicant respectfully submits that the teachings of Roreger cannot contemplate or suggest the inventions defined in claims 1 and 13, as well as the inventions in claims 2-10 that depend on claim 1.

For example, the teachings of Roreger, at best, propose:

- the gel film being produced of components having optimum skin and mucous membrane tolerance (column 2, lines 15-17),
- In a preferred embodiment, the substrate with which the gel film interacts is damaged skin (column 6, lines 60-61),
- In another preferred embodiment, the substrate with which the gel film interacts is intact skin (column 7, lines 61-62),
- By this way of alternating release of active substances, it is possible, e.g. to consider more purposeful specific therapy schemes, which is usual in the peroral application of medicines, but without the disadavantages of peroral medicines (column 9, line 65 - column 10, line 2), and
- According to a further preferred embodiment, the substrate with which the gel film interacts is mucous membrane (column 10, lines 29-30).

From the above, it is readily apparent that the teachings of Roreger are concerned with a flexible, hydrophilic gel film that is applied to the skin or mucous membrane, not an orally administered agent containing a drug that is released in the digestive tract, as required in present claims 1 and 13. While the Official action stated that the presently claimed orally administered agent is "intended use" and not considered a patentable limitation during prosecution of composition claims before the USPTO, applicant respectfully submits that this position is not

correct for the present claims. The presently claimed invention is directed to solving problems unique to an orally administered agent containing a drug. It is well established in the case law that if limitations in the preamble of a claim necessarily give meaning to the claim and properly define the invention, then such limitations must be considered when determining the patentability of the claims. The predecessor court of the Court of Appeals for the Federal Circuit (CAFC), namely, the Court of Custom and Patent Appeals (CCPA) summarized this approach in *Kropa v. Robie*, 88 USPQ 478 (1951), after reviewing some 37 cases that turned on the limiting nature of the preambles to the claims in suit. See also *Loctite Corp. v. Ultraseal Ltd.*, 228 USPQ 90, 94 (Fed. Cir. 1985). According to the court in *Kropa*:

> [T]he preamble has been denied the effect of a limitation where... the claim or [interference] count apart from the introductory clause completely defined the subject matter [of the invention], and the preamble merely stated a purpose or intended use of that subject matter. On the other hand, in those... cases where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts.

Examples of preambles cited in *Kropa* as expressly or impliedly held to express a limitation in the claims are "An insecticide" and "An insecticide composition." Applicant respectfully submits that the claims in this application present precisely the situation where the preamble of a claim has been held to express a limitation in the claim in *Kropa*. The preamble of applicant's claims distinguishes the presently claimed invention by defining an *orally administered agent* containing a drug that is released in the digestive tract, which area of technology is unique and presents significantly more difficulties compared to, for example, the flexible, hydrophilic gel film that is applied to the skin or mucous membrane, such as proposed by Roreger. Therefore, applicant respectfully submits that teachings that are not concerned with an *orally administered agent* containing a drug that is released in the digestive tract, such

as those of Roreger, could not possibly motivate one of ordinary skill in the art to the presently claimed orally administered agent.

Furthermore, the teachings of Roreger propose that in the case of buccal or sublingual application of the gel film, the active substance can be released to the system circulation via the mucous membrane of the mouth. In this case, the gel film has a back layer that prevents removal of larger amounts of active substance from the gel film via the saliva and prevents large amounts of active substance from being absorbed gastrointestinally after choking (column 10, lines 54-60 of Roreger). Accordingly, it would be readily apparent to those persons skilled in the art that the flexible, hydrophilic gel film proposed by Roreger is not an orally administered agent containing; *inter alia*, a drug that is released in the digestive tract, as required in present claims 1 and 13.

Furthermore, given the discussion of choking at column 10, lines 54-60 of Roreger, applicant respectfully submits that it is impossible for these teachings to contemplate or suggest that *the agent is swallowed without getting stuck in a trachea*, as required in present claim 13. In particular, applicant respectfully submits that it is impossible and improper to modify the teachings of Roreger to include an *agent being swallowed without getting stuck in a trachea*, when the teachings of Roreger propose an advantage to the gel film therein choking the user. The courts have repeatedly held that references cannot properly be modified or combined, if the effect would destroy the invention on which reference is based. *In re Randol and Redford*, 165 USPQ 586 (CCPA 1970); *Ex parte Thompson*, 184 USPQ 558 (PTO Bd. Pat Apps. & Interf. 1974); *Ex parte Hartman*, 186 USPQ 336 ((PTO Bd. Pat Apps. & Interf. 1976).

At least for the foregoing reasons, applicant respectfully submits that the inventions defined in claims 1-10 and 13 are patently distinguishable from the teachings of Roreger. Therefore, applicant respectfully requests that the examiner reconsider and withdraw this rejection and formally allow claims 1-10 and 13, together with withdrawn claims 10 and 11.

While it is believed that the present response is a complete and proper response to the Official action mailed August 1, 2007, should the examiner have any comments or questions, it is respectfully requested that the undersigned be telephoned at the below listed number to resolve any outstanding issues.

In the event this paper is not timely filed, applicant hereby petitions for an appropriate extension of time. The fee therefor, as well as any other fees which become due, may be charged to our deposit account No. 50-1147.

Respectfully submitted,

R. Eugene Varndell, Jr.
Reg. No. 29,728

Posz Law Group, PLC
12040 South Lakes Drive
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Reston, VA 20191
Phone 703-707-9110
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Eiji NOGAMI	Atty. Docket No.: 24-009-TB
Application No.: 10/690,811	Art Unit: 1616
Filed: October 23, 2004	Examiner: Edward J. Webman
Title: ORALLY ADMINISTERED AGENT AND AN ORALLY ADMINISTERED AGENT/SUPPORTING SUBSTRATE COMPLEX	

Mail Stop: Office of Initial Patent Examination Filing Receipt Corrections
Commissioner for Patents
Alexandria, VA 22314

Date: November 20, 2007

Copy

SECOND REQUEST FOR CORRECTED FILING RECEIPT

Sir:

Applicant respectfully requests a corrected filing receipt in connection with the above-identified application. The filing receipt mailed on December 12, 2005 correctly contains the international priority information (i.e., "This application is a CON of PCT/JP02/03920 04/19/2002") under "Domestic Priority."

Unfortunately, this same information is also included under "Foreign Applications," which is not correct. For this reason, applicant respectfully requests that only the information under the heading "Foreign Applications" be changed by deleting reference to the international application, "JAPAN PCT/JP02/03920 04/19/2002." In other words, applicant respectfully requests that the information under the heading "Foreign Applications" in the Official filing receipt be changed from:

"Foreign Applications
JAPAN 2001-125804 04/24/2001
JAPAN PCT/JP02/03920 04/19/2002"

to:

"Foreign Applications
JAPAN 2001-125804 04/24/2001"

For the foregoing reasons, applicant respectfully requests the issuing of a corrected filing receipt and the mailing of the same to the undersigned, where the "Foreign Applications" section refers only to "JAPAN 2001-125804 04/24/2001." Applicant is attaching the following information hereto for facilitating this request:

- A copy of the Official filing receipt with indicated corrections marked thereon (one page);
- A copy of Application Data Sheet (two pages); and
- A copy of originally-filed Utility Patent Application Transmittal Form PTO/SB/05 (one page).

In the event that there are any questions concerning this request, applicant respectfully requests that the undersigned be telephoned at the below-listed number to resolve any outstanding issues.

Please charge any unforeseen fees that may be due to deposit account No. 50-1147.

Respectfully submitted,

R. Eugene Varndell, Jr.
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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
10/690,811	10/23/2003	1616	1740	24-009-TB	12	1

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DEC 5

CONFIRMATION NO. 5426
CORRECTED FILING RECEIPT

OC000000027053135

Date Mailed: 12/04/2007

Copy

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Eiji Nogami, Saitama-shi, JAPAN;

Power of Attorney: The patent practitioners associated with Customer Number 23400

Domestic Priority data as claimed by applicant

This application is a CON of PCT/JP02/03920 04/19/2002

Foreign Applications

JAPAN 2001-125804 04/24/2001

If Required, Foreign Filing License Granted: 01/23/2004

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 10/690,811**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No